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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,655	01/07/2002	Andrew Darrow	ORT-1566	3674

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03/24/2004

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,655

Applicant(s)

DARROW ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 26 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

Applicant's Amendment filed December 15, 2003, to the title and to claims 25 and 26, and adding the new claims 38-32, has been entered. The amendment to claim 25 introducing the phrase, "corresponding to", requires restatement of rejections of record under 35 U.S.C. § 112, first paragraph, for lack of adequate written description and lack of enablement, and requires a new rejection under 35 U.S.C. § 112, second paragraph, of claims herein for indefinite description, and further requires restatement of the rejections of record over the prior art.

Claim Rejections - 35 USC §112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26 and 28-32 are rejected, essentially for reasons of record, under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed December 15, 2003, have been fully considered but they are not persuasive. Applicant suggests that the amended claims set forth subject matter adequately described by the specification but the term "corresponding to" in the independent claim 25, affecting claims 26 and 28-32 depending therefrom, vitiates this argument. This is because the specification does not define the term "corresponding to" which must be construed according to statements at lines 26-29 at page 2 therein to express a scope including "homologues", "genomic equivalents" and "mutant forms" of the native serine protease T having the amino acid sequence set forth in SEQ ID NO:7. Proteases that are "homologues", "genomic equivalents" and "mutant forms" will indeed

"correspond to" the native protease T amino acid sequence set forth in SEQ ID NO:7 but the specification fails to provide an adequate written description of such undisclosed, "corresponding" proteases where there is no evidence that Applicant possessed any "corresponding" "homologues", "genomic equivalents" or "mutant forms" of the human serine protease T having the amino acid sequence set forth in SEQ ID NO:7 at the time the parent application was filed other than the fusion protein having the amino acid sequence set forth in SEQ ID NO:9.

The fusion protein of SEQ ID NO:9 comprises the amino acid sequence of the protease T catalytic domain and it is agreed that Applicant need not disclose alternative fusion proteins comprising this native catalytic domain to demonstrate an inherent possession of generic fusion proteins that also comprise the native catalytic domain. Neither the full-length serine protease T having the entire amino acid sequence of SEQ ID NO:7 nor the integral fusion protein having the entire amino acid sequence of SEQ ID NO:9 will be present in the cleaning compositions of claims 25, 26 and 28-32. Instead, only the mature protease T, essentially its catalytic domain, will be present in the claimed cleaning compositions according to the teachings of the specification and nothing in the specification shows that Applicant had determined, or even contemplated, those positions among the carboxyl-proximal 260 amino acids of the T protease that might be altered, nor the nature of any amino acid substitution, deletion or addition that might provide a "homologue", "genomic equivalent" or "mutant form" of this catalytic domain. The rejection of record is sustained because the specification provides no written description demonstrating Applicant's possession of cleaning compositions that comprise "corresponding" proteases as recited in the amended claim 25.

Claims 25, 26 and 28-32 are rejected, essentially for reasons of record, under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for cleaning compositions comprising a human serine protease T having the catalytic domain amino acid sequence set forth in SEQ ID NO:7, does

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not reasonably provide enablement for cleaning compositions comprising proteases having amino acid sequences that "correspond to" the catalytic domain of the protease comprised by SEQ ID NO:7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed December 15, 2003, have been fully considered but they are not persuasive. Applicant suggests that the amended and new claims recite subject matter enabled by the specification but the ambiguous term, "corresponding to", introduced into claim 25, and affecting claims 26 and 29-32 depending therefrom, vitiate this argument. It is agreed that the specification enables the preparation of cleaning compositions comprising a protease having the catalytic domain present in the amino acid sequence set forth in SEQ ID NO:7 and in the zymogen-protease T fusion protein having the amino acid sequence set forth in SEQ NO:9 where a few relative amino acid substitutions are disclosed at the amino-proximal border of the catalytic domain of the zymogen-protease T fusion protein having the amino acid sequence set forth in SEQ ID NO:9. The rejection of record is sustained, however, because the specification does not enable the preparation of cleaning compositions embraced by claims 25, 26 and 28-30 that comprise "homologues", "genomic equivalents" and "mutant forms" of a mature protease T where it fails to teach the preparation of any "homologues", "genomic equivalents" and "mutant forms" of the catalytic domain of the native human protease T that sustain arbitrary assignments of any or all amino acid deletions, additions, or substitutions altering final 260 amino acids of the amino acid sequence of SEQ ID NO:7.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 26 and 28-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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This new ground rejection is required because the amendment to claim 25 that introduces the phrase "corresponding to" renders the claim ambiguous, thus indefinite, where the artisan and the public seeking to construe the scope of the amended claim can know neither the degree nor the nature of the "correspondence" Applicant intends. Claims 26 and 28-32 are subject to this rejection because they incorporate the indefinite limitation of claim 25 from which they depend without resolving its ambiguity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 25, 26 and 28-32 are rejected, essentially for reasons of record, under 35 U.S.C. § 103(a) as being obvious over Antalis et al., WO 98/36054, Samal et al., U.S. Patent 5,278,062, and Egelrud et al., U.S. Patent 5,834,290, in view of Hellgren et al., U.S. Patent 4,801,451, all of record.

Applicant's arguments filed December 15, 2003, have been fully considered but they are not persuasive because the amendment to claim 25 introducing the term "corresponding to" cannot distinguish a protease of a claimed cleaning composition over the catalytic domain of the protease taught by Antalis et al. where their SP003LA protease is entirely identical to the catalytic domain of the native protease T disclosed herein, lacking only a portion of the signal peptide region to share complete identity with the protease T amino acid sequence of SEQ ID NO:7 of the instant application and

sharing the same activation site sequence, thus is clearly a "corresponding" molecule. See, Figure 20C and SEQ ID NO:30, at pages 10, 18, and Example 15 at pages 52-53 and claims 19-21, 26, and 27. Antalis et al. generally teach preparation of expression vectors and host cells comprising a nucleotide sequence encoding a SP003LA serine protease in a context for expression by the host cell, which may be a prokaryotic or eukaryotic host cell, see pages 38 and 39. Antalis et al. need not teach preparation of a particular expression vector comprising their protease-encoding nucleotide sequence, or transformation of a particular host cell with such an expression vector, to render the production of this "corresponding" protease present in compositions of claims 25, 26 and 28-32 herein obvious to one of ordinary skill in the art where a great variety of such vectors and host cells were well-known and commonly-used in the art at the time the invention was made.

Egelrud et al. teach the insertion of a polynucleotide encoding a human serine protease having the amino acid sequence set forth in their SEQ ID NO:2 into an expression vector, the transformation of host cells with the vector, and the recombinant expression of the encoded serine protease by the host cells in order to recover it from the cells and incorporate it in cleaning compositions of claims 25 and 26 herein comprising surfactants, binders, and other compounds recited in the new claims 28-31 herein as well as to incorporate it in soaps and shampoos comprising materials recited in the new claim 32 herein. See cols. 9-20, and col. 22, lines 25-46, and Figs. 15 and 18. Samal et al. similarly teach the transformation of an eukaryotic host cell with an expression vector comprising a polynucleotide encoding an eukaryotic serine protease, the induction of the recombinant expression of the encoded serine protease by the transformed host cells, the recovery of the protease from the transformed cells, and the formulation of the recovered serine protease with surfactants, binders, bleaches, and

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ancillary compounds to prepare a detergent compositions of claims 25, 26 and 28-32 herein useful for laundering fabrics. See cols. 4-6 and Fig. 3. Hellgren et al. show that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared a detergent composition comprising an animal serine protease, such as the proteases of Antalis et al. or Egelrud et al., where Hellgren et al. teach that an animal serine protease may be both formulated in compositions for topical cleaning of human skin and formulated in detergent compositions of claims 25 and 26 herein comprising components of the new claims 29-32 herein for laundering fabrics, see cols. 2-9.

The rejection of record is sustained because it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of the recombinant expression of the "corresponding" protease - a protease that is indeed identical throughout its catalytic domain - of Antalis et al. with the teachings of Egelrud et al., Samal et al. and Hellgren et al. and to thus formulate cleaning compositions comprising a recombinantly-produced protease of Antalis et al. This is because both Egelrud et al. and Samal et al. teach that human and other eukaryotic serine proteases may be recombinantly expressed by host cells transformed with expression vectors comprising polynucleotides encoding the proteases and that the proteases may then be recovered from such cells upon expression for formulation in cleaning compositions such as laundry detergent compositions and because Hellgren et al. teach that an animal serine protease may be formulated in cleaning compositions for cleaning the skin and for laundering fabrics.

Conclusion

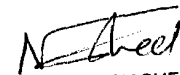
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
March 22, 2004


NASHAAT T. NASHED
PRIMARY EXAMINER